

Application no.: 09/974,882

Docket no.: GTI-1320-CON1

**REMARKS**

Upon entry of the above amendments, claims 21 and 24-34 will be pending. The Applicants reserve the right to pursue subject matter that will no longer be pending after the amendments above are entered or which has not yet been pursued in a related application. The claim amendments add no new matter as they find basis in the specification in paragraphs 0005, 0006, 0017, 0025 and 0026, and claims 9, 10, 11 and 22 of the patent application as originally filed, for example. Thus, entry of the above amendments is proper.

**Priority and Objections to the Specification**

The Office objected to priority information introduced by the Applicants in paragraph [0001] of the present patent application. It was stated in the Office action that the priority patent applications did not provide basis for a negative limitation "wherein said cell is not a plant cell," or a chromosome encapsulated in a liposome. The Office also objected to the specification because of the negative limitation. Including patent application no. 60/110,950 in paragraph [0001] was objected to as it allegedly was not copending at the time to present patent application was filed.

The Applicants respectfully submit that the objections are moot in view of the amendments to the specification. Amended paragraph [0001] does not include a reference to application no. 60/110,950, and amended paragraph [0025] does not include a negative limitation that excludes plant cells. As the parent patent application, application no. 09/453,610, provides basis for a chromosome encapsulated in a liposome in original claim 22, for example, the related application description in paragraph [0001] is proper and no prohibited new matter is present in the subject patent application.

Amended claims 21 and 26 no longer include the negative limitation, and therefore, they find basis in the priority patent applications. Accordingly, claims in the subject patent application are entitled to priority dates of December 3, 1999 and December 4, 1998. It is respectfully requested that the Office acknowledge the related patent application information in amended paragraph [0001] and withdraw the new matter objection to the specification.

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Rejection Under 35 U.S.C. § 102(b)

The Office rejected claims 21 and 24-26 under 35 U.S.C. § 102(b) for alleged anticipation by WO 00/34436, which published on June 15, 2000. It is respectfully submitted that this rejection is moot because the amended claims, which find basis in the priority patent applications, are afforded priority dates of December 3, 1999 and December 4, 1998. Accordingly, WO 00/34436 is not prior art and it is respectfully requested that the Office withdraw the rejection under 35 U.S.C. § 102(b).

Written Description Rejection Under 35 U.S.C. § 112, First Paragraph

The Office rejected claims 21 and 24-26 under 35 U.S.C. § 112, first paragraph, as the specification allegedly did not provide evidence that the Applicants had possession of the claimed subject matter at the time the patent application was filed. It is respectfully submitted that this rejection is moot because the amended specification and claims do not include the negative limitation relating to plant cells objected to by the Office. Thus, it is respectfully requested that the Office withdraw the written description rejection under 35 U.S.C. § 112, first paragraph.

Enablement Rejection Under 35 U.S.C. § 112, First Paragraph

The Office rejected claims 21 and 24-26 under 35 U.S.C. § 112, first paragraph, as the specification allegedly does not enable a method where "cells into which the chromosomes are introduced are implanted as part of an ex vivo gene therapy protocol." The Office, however, stated that the specification is enabling for a method of in vitro introduction of at least one chromosome into a cell. The Applicants have amended claims 21 and 26 to specify that the methods are for introducing at least one chromosome into a cell in vitro, and therefore, the claims are enabled in accordance with the Office's analysis of the specification. Accordingly, is respectfully requested that the Office withdraw the rejection of claims 21 and 24-26 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement.

Amending the term "ex vivo" to "in vitro" is not narrowing as the claims formerly specified that the cells were transformed with a chromosome outside a subject, i.e., ex vivo, which did not require that the ultimate goals of gene therapy were attained after transformed cells were returned and implanted in a subject. Similarly, the amended claims do not require that the ultimate goals of gene therapy are attained if cells successfully transformed in vitro are implanted into a subject. The

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amended claims are directed to electroporation-mediated chromosome translocation outside of a subject, and cells resulting from such processes can be utilized further in a procedure selected by an artisan of ordinary skill (e.g., synthesizing protein, synthesizing DNA with repeating units, generating transgenic animals and introducing the cells into a subject).

Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office rejected claims 21 and 24-26 under 35 U.S.C. § 112, second paragraph, as the term "substantially simultaneously" allegedly was not clear. The Applicants respectfully submit that this rejection is moot because the amended claims no longer include the term "substantially simultaneously." The amended claims are not narrowed because this term has been removed. Accordingly, it is respectfully requested that the Office withdraw the rejection of claims 21 and 24-26 under 35 U.S.C. § 112, second paragraph.

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**CONCLUSIONS**

The Applicants respectfully submit that, after entry of the above amendments, all pending claims will be in condition for allowance, and they earnestly solicit an early notice to such effect. Should any issues or questions remain, the Examiner is encouraged to telephone the undersigned representative at (858) 623-9470 so that they may be promptly resolved.

In the unlikely event the transmittal letter is separated from this document and the Office determines that an extension and/or other relief is required, Applicants petition for any required relief, including extensions of time, and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to the credit card disclosed in form PTO-2038 filed with this document.

Respectfully submitted,

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